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**Declaration under Rule 4.17:**

— of inventorship (Rule 4.17(iv)) for US only

**Published:**

— with international search report

— before the expiration of the time limit for amending the claims and to be republished in the event of receipt of amendments

(88) Date of publication of the international search report:  
4 November 2004

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

(54) Title: THERAPEUTIC AND PROPHYLACTIC VACCINE FOR THE TREATMENT AND PREVENTION OF PAPILLOMAVIRUS INFECTION

(57) Abstract: This invention provides compositions including a chimera of papillomavirus capsid polypeptide L2 and polypeptide including an immunotherapeutic epitope, and GST fusions thereof. The present invention also provides complexes comprising chimeras of papillomavirus L2 polypeptides non-covalently associated with papillomavirus L1 polypeptides, and GST fusions thereof. These compositions may be used to elicit immune responses in a patient to papillomavirus. Therapeutic and prophylactic vaccines for the prevention and treatment of viral infection, especially papillomavirus infection and cervical cancers and warts associated therewith, made from compositions of this invention, are also disclosed. Nucleic acids and expression vectors coding for compositions of this invention are also disclosed.

## PATENT COOPERATION TREATY

RECEIVED

AUG 26 2004

From the INTERNATIONAL SEARCHING AUTHORITY

To:  
CAROL W. BURTON  
HOGAN & HARTSON, LLP  
1200 17TH STREET, SUITE 1500  
DENVER, CO 80202

PCT

HOGAN &amp; HARTSON, LLP

NOTIFICATION OF TRANSMITTAL OF  
THE INTERNATIONAL SEARCH REPORT  
OR THE DECLARATION

(PCT Rule 44.1)

Date of Mailing (day/month/year) <b>23 AUG 2004</b>	
Applicant's or agent's file reference CU2002095H	FOR FURTHER ACTION See paragraphs 1 and 4 below
International application No. PCT/US04/00196	International filing date (day/month/year) 06 January 2004 (06.01.2004)
Applicant REGENTS OF THE UNIVERSITY OF COLORADO	

1. ☒ The applicant is hereby notified that the international search report has been established and is transmitted herewith.

**Filing of amendments and statement under Article 19:**

The applicant is entitled, if he so wishes, to amend the claims of the international application (see Rule 46):

**When?** The time limit for filing such amendments is normally two months from the date of transmittal of the international search report.

**Where?** Directly to the International Bureau of WIPO, 34, chemin des Colombettes  
1211 Geneva 20, Switzerland, Facsimile No.: (41-22) 740.14.35

For more detailed instructions, see the notes on the accompanying sheet.

2. ☐ The applicant is hereby notified that no international search report will be established and that the declaration under Article 17(2)(a) to that effect is transmitted herewith.

3. ☐ With regard to the protest against payment of (an) additional fee(s) under Rule 40.2, the applicant is notified that:

- ☐ the protest together with the decision thereon has been transmitted to the International Bureau together with the applicant's request to forward the texts of both the protest and the decision thereon to the designated Offices.
- ☐ no decision has been made yet on the protest; the applicant will be notified as soon as a decision is made.

**4. Reminders**

Shortly after 18 months from the priority date, the international application will be published by the International Bureau. If the applicant wishes to avoid or postpone publication, a notice of withdrawal of the international application, or of the priority claim, must reach the International Bureau as provided in Rules 90 bis.1 and 90 bis.3, respectively, before the completion of the technical preparations for international publication.

Within 19 months from the priority date, but only in respect of some designated Offices, a demand for international preliminary examination must be filed if the applicant wishes to postpone the entry into the national phase until 30 months from the priority date (in some Offices even later); otherwise the applicant must, within 20 months from the priority date, perform the prescribed acts for entry into the national phase before those designated Offices.

In respect of other designated Offices, the time limit of 30 months (or later) will apply even if no demand is filed within 19 months.

See the Annex to Form PCT/IB/301 and, for details about the applicable time limits, Office by Office, see the *PCT Applicant's Guide*, Volume II, National Chapters and the WIPO Internet site.

Name and mailing address of the ISA/US  
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Authorized officer  
A. R. Salimi

Telephone No. (571) 272-1600

Form PCT/ISA/220 (April 2002)

(See notes on accompanying sheet)

# PATENT COOPERATION TREATY

## PCT

### INTERNATIONAL SEARCH REPORT

(PCT Article 18 and Rules 43 and 44)

Applicant's or agent's file reference CU2002095H	<b>FOR FURTHER ACTION</b>	see Notification of Transmittal of International Search Report (Form PCT/ISA/220) as well as, where applicable, item 5 below.
International application No. PCT/US04/00196	International filing date ( <i>day/month/year</i> ) 06 January 2004 (06.01.2004)	(Earliest) Priority Date ( <i>day/month/year</i> ) 10 January 2003 (10.01.2003)
Applicant REGENTS OF THE UNIVERSITY OF COLORADO		

This international search report has been prepared by this International Searching Authority and is transmitted to the applicant according to Article 18. A copy is being transmitted to the International Bureau.

This international search report consists of a total of 24 sheets.



It is also accompanied by a copy of each prior art document cited in this report.

**1. Basis of the Report**

a. With regard to the **language**, the international search was carried out on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.



the international search was carried out on the basis of a translation of the international application furnished to this Authority (Rule 23.1(b)).

b. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international search was carried out on the basis of the sequence listing:



contained in the international application in written form.



filed together with the international application in computer readable form.



furnished subsequently to this Authority in written form.



furnished subsequently to this Authority in computer readable form.



the statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.



the statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

2. ☐ Certain claims were found unsearchable (See Box I).

3. ☐ Unity of invention is lacking (See Box II).

4. With regard to the **title**,



the text is approved as submitted by the applicant.



the text has been established by this Authority to read as follows:

5. With regard to the **abstract**,



the text is approved as submitted by the applicant.



the text has been established, according to Rule 38.2(b), by this Authority as it appears in Box III. The applicant may, within one month from the date of mailing of this international search report, submit comments to this Authority.

6. The figure of the **drawings** to be published with the abstract is Figure No. \_\_\_\_\_



as suggested by the applicant.



because the applicant failed to suggest a figure.



because this figure better characterizes the invention.



None of the figures

# INTERNATIONAL SEARCH REPORT

PCT/US04/00196

**Continuation of B. FIELDS SEARCHED Item 3:**  
WEST, DERWENT, NPL, MEDLINE, CAPLUS  
search terms: papilloma virus, capsid protein, L1, L2, chime?

# INTERNATIONAL SEARCH REPORT

International application No.

PCT/US04/00196

## A. CLASSIFICATION OF SUBJECT MATTER

IPC(7) : A61K 39/12

US CL : 424/204.1

According to International Patent Classification (IPC) or to both national classification and IPC

## B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 424/204.1

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)  
Please See Continuation Sheet

## C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	LI et al. Expression of the human papillomavirus type 11 L1 capsid protein in Escherichia coli: characterization of protein domains involved in DNA binding and capsid assembly. Journal Virology. April 1997, Vol. 71, No. 4, pages 2988-2995.	1-43
A	HAGENSEE et al. Self-assembly of human papillomavirus type 1 capsids by expression of the L1 protein alone or by coexpression of the L1 and L2 capsid proteins. Journal Virology. January 1993, Vol. 67, No. 1, pages 315-322.	1-43
A	CHEN et al. Papillomavirus capsid protein expression in Escherichia coli: purification and assembly of HPV11 and HPV16 L1. J. Mol. Biol. 16 March 2001, Vol. 307, No. 1, pages 173-182.	1-43
A	TOUZE et al. The nine C-terminal amino acids of the major capsid protein of the human papillomavirus type 16 are essential for DNA binding and gene transfer capacity. FEMS Microbiol Lett. 01 August 2000, Vol. 189, No. 1, pages 121-127.	1-43
A	OKUN et al. L1 interaction domains of papillomavirus 12 necessary for viral genome encapsidation. Journal of Virology. May 2001, Vol. 75, No. 9, pages 4332-4342.	1-43



Further documents are listed in the continuation of Box C.



See patent family annex.

* Special categories of cited documents:	"I" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"A" document defining the general state of the art which is not considered to be of particular relevance	"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"E" earlier application or patent published on or after the international filing date	"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)	"&" document member of the same patent family
"O" document referring to an oral disclosure, use, exhibition or other means	
"P" document published prior to the international filing date but later than the priority date claimed	

Date of the actual completion of the international search

04 August 2004 (04.08.2004)

Name and mailing address of the ISA/US

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Alexandria, Virginia 22313-1450

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Date of mailing of the international search report

23 AUG 2004

Authorized officer

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Form PCT/ISA/210 (second sheet) (July 1998)

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## INTERNATIONAL SEARCH REPORT

## C. (Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	KIRNBAUER et al. Efficient self-assembly of human papillomavirus type 16 L1 and L1-L2 into virus-like particles. Journal Virology. December 1993, Vol. 67, No. 12, pages 6929-6936.	1-43